REMARKS

I. Preliminary Matters

Claims 1-5, 8-14 and 17-21 are pending in the application. Claims 13-14 and 17-19 are withdrawn from consideration. Claims 1-5, 8-12 and 20-21 are rejected. Claims 1-3 and 11-12 are canceled without prejudice or disclaimer.

Claims 4 and 13 are amended to remove recitation of a pharamaceutical drug. Claim 13 is further amended to recite the more conventional "comprising" language in place of "characterized by". Claim 20 is amended to recite that the radial spherical crystallization product is mixed with a drug, as supported, for example, in Example 2. Claim 21 is amended to remove recitation of a drug carrier, as being redundant in view of the amendment to claim 4.

New claim 22 is added to recite a mixture of the radial spherical crystallization product and a pharmaceutical drug, with support, for example, in Example 2.

No new matter is added. Accordingly, entry of the Amendment is respectfully requested.

Additionally, it appears that the Examiner inadvertently failed to indicate the filing date of the Drawings, filed December 9, 2005, which are indicated as accepted in the Office Action Summary. Accordingly, Applicants respectfully request the Examiner to confirm the filing date of the accepted Drawings.

Furthermore, Applicants confirm election of Group I for consideration on the merits in response to the Restriction Requirement.

II. Response to Claim Objections

At page 4 of the Office Action, claim 20 [*sic.*] is objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, claim 20 is objected to for reciting "a carrier" while claim 4, from which claim 20 [sic.] depends, recites "a drug carrier."

Applicants respectfully submit that claim 20 does not recite "a carrier," but claim 21 does. Furthermore, claim 21 is amended to remove the recitation of a carrier as being redundant in view of the recitation in claim 4. Accordingly, the objection to claim 21 is rendered moot.

III. Response to Claims Rejections Under 35 U.S.C. § 112

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully submit that in view of the cancellation of claim 1, the § 112 rejection of the claim is rendered moot.

IV. Response to Claim Rejections Under 35 U.S.C. § 102

1. Claims 1, 3, 4, 5, and 8-12 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hanna et al. (US 6,063,18).

2. Claims 1, 3, 4, 5, and 9-12 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Reverchon et al. (Powder Technol., 114, pp. 17-22; "Reverchon")

Applicants respectfully traverse, at least for the following reasons.

Initially without acquiescing to the merits, claims 1, 3, 11 and 12 are canceled.

Applicants submit that claims 4, 5 and 8-10 are product-by-process claims, and their

patentability is based on the product itself. Applicants submit herewith a Rule 132 Declaration of Mr. Takeuki Furudate to demonstrate that the presently claimed product is distinguishable from the products obtained using the processes of Hanna and Reverchon.

Specifically, the Rule 132 Declaration presents data demonstrating that the radial spherical crystallization product as recited in the present claims has unexpectedly superior properties as compared to the product of Hanna, which is considered to be the closest specifically disclosed product of the cited references. See, for example, the particle formation of the presently claimed product when compared to the particle formation of the product of Hanna, as discussed in the Rule 132 Declaration. Furthermore, experimental results summarized in Table 2 of the Rule 132 Declaration (reproduced below) shows that the release rate of the presently claimed product is superior to that of the product of Hanna.

	Starting total amount of crystallization product filled into the capsules (mg) (4 capsules for each experiment, each capsule having 10 mg of product)	Ending total amount of crystallization product remaining in the devices and capsules after inhaling (mg)	Release rate
Crystallization product of the present invention (lactose)	40.62	6.01	85.2
Crystallization product similar to Hanna's product (lactose)	40.52	24.98	38.4

As the above results are mainly caused by the method of making of the crystallization product, the crystallization product formed from a drug carrier and the crystallization product formed from a drug substance, such as salbutamol, may be expected to yield similar results.

Moreover, the method of making the crystallization product of the present invention is completely different from the method of making Hanna's product or Reverchon's product.

Accordingly, Applicants respectfully submit that the presently claimed product is distinguishable over both Hanna and Reverchon. Therefore, reconsideration and withdrawal of the § 102 rejections are respectfully requested.

V. Response to Claims Rejections Under 35 U.S.C. § 103

Claims 1-5, 8-12, 20 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanna, Reverchon, Yianneskis *et al.* (US 5,975,076; "Yianneskis") and Radhakrishnan *et al.* (US 5,192,528; "Radhakrishnan").

Applicants respectfully traverse, at least for the following reasons.

Initially without acquiescing to the merits, claims 1-3 and 11-12 are canceled.

As discussed above, the presently claimed product is distinguishable over the products made using the processes of Hanna and Reverchon. Neither Yianneskis nor Radhakrishnan cures the deficiencies in Hanna and Reverchon with respect to the presently claimed invention. Accordingly, claims 4, 5, 8-10, 20 and 21 are patentable over the combination of Hanna, Reverchon, Yianneskis and Radhakrishnan, at least by virtue of their dependence from claim 4. Newly added claim 22 is also patentable over the above combination of references, at least by virtue of its dependence from claim 4.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the § 103 rejection of claims 4, 5, 8-10 and 20-22.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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